

REPORT OF A
GOOD LABORATORY PRACTICE INSPECTION:
COMPLIANCE REVIEW AND STUDY AUDITS
CONDUCTED PURSUANT TO THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

LABORATORY: Smithers Viscient
Carolina Research Center
2900 Quakerbush Road
Snow Camp, NC 27349

INSPECTION NUMBER: 20191894451

RESPONSIBLE OFFICIAL: Mr. Gus Zieske
gzieche@smithers.com

DATES OF INSPECTION: December 4-6, 2018

SIGNATURES:

Inspector/Auditor:


Elmer Griffin, Compliance Inspector
OC/MAMPD

Feb 12, 2019
Date

Administrator/
Technical Reviewer:

DANIEL MYERS

Digitally signed by DANIEL MYERS
Date: 2019.03.01 15:24:25 -07'00'

Date

Approver:

FRANCISCA LIEM

Digitally signed by FRANCISCA LIEM
Date: 2019.03.10 12:20:12 -04'00'

Date

SUMMARY OF FINDINGS

A US EPA FIFRA GLP compliance inspection and four study audits were conducted at Smithers Viscient, Carolina Research Center for compliance with FIFRA Books and Records Regulations: 40 CFR §169 and FIFRA Good Laboratory Practice Standards: 40 CFR §160. No ongoing study was audited. The study audits served as a partial basis for the GLP compliance review of current laboratory practices and procedures.

No adverse findings were observed for the compliance review and study audits.

I. INTRODUCTION

A FIFRA Good Laboratory Practice Standards compliance review and study audits were conducted at the request of the Office of Compliance (OC), Office of Enforcement and Compliance Assurance (OECA). This was a randomly selected and neutral scheme inspection. The inspection and study audits were conducted by Elmer Griffin, GLP Program.

II. OPENING CONFERENCE

An opening conference began on December 4, 2018 in the facility's conference room. The company officials present during the opening conference were Mr. Zieske and Ms. Barbara Shipley, Director, Quality System.

Official credentials were presented to Mr. Zieske. The FIFRA Notice of Inspection was signed by Mr. Zieske. (Exhibit 1).

III. NARRATIVE

GLP COMPLIANCE INSPECTION

The compliance inspection was accomplished through review of laboratory operations, interviews with study personnel, facility tour, equipment maintenance and calibration records and archive records. No adverse findings were observed.

STUDY AUDIT

The study audits were accomplished through review of available raw data, records, and reports; interviews with study personnel; and review of laboratory operations. The audit was based on: completeness of the raw data, conformance of the raw data to the study report findings and conclusions, adherence to the GLP Standards requirements and to available and appropriate SOPs and protocols.

The following aspects of the studies were reviewed: protocol, final study report, recordkeeping, quality assurance, test system (specimen) receipt and distribution, equipment maintenance and calibration records and the administration, use, and testing of the test substance.

1. Colony Feeding Study Evaluating the Chronic Effects of Chothianidin- Fortified Sugar Diet on Honey Bee (*Apis mellifera*) Colony Performance Under Free Foraging Conditions.
Product Tested: 59639-173. (EPA MRID No. 50312501)
No significant finding was observed.
2. Zebra Finch (*Taeniopygia guttata*) Dietary Acute Toxicity Test.
(EPA MRID No. 50316101)
No significant finding was observed.
3. Thiamethoxam 25WG (A9584C) - Residues in Leaves, Flowers, Pollen, and Nectar of Ornamental Plants After Foliar or Soil Applications in the USA: Final Report.
(EPA MRID No. 50425903)
No significant finding was observed.
4. Magnitude of Residues of Sulfoxaflor in Nectar, Pollen, and Whole Plants Following Foliar Application of GF-2032 to Canola. Products Tested: 62719-631. (EPA MRID: 50355204)
No significant finding was observed.

IV. EXIT CONFERENCE

The exit conference was held on December 06, 2018 to review the findings of the GLP compliance review and study audits. The inspector the facility with a FIFRA Receipt for Samples: Form 3540-3 (Exhibit 2), and an Inspection Observation: Form 3540-38 (Exhibit 3).

V. LIST OF EXHIBITS and SIGNATURE

Exhibit 1	FIFRA Notice of Inspection
Exhibit 2	FIFRA Receipt of Samples
Exhibit 3	Inspection Observations